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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/578,534	05/24/00	CROSSMAN D	MSA-017.02

025181
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HM12/0705

EXAMINER	
MYERS, C	
ART UNIT	PAPER NUMBER
1655	7

DATE MAILED: 07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/578,534	Applicant(s) CROSSMAN ET AL.	
	Examiner Carla Myers	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2000* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-79* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

1. ***RESTRICTION***

Prior to setting forth the restriction requirement, it is pointed out that Applicants have presented the methods of claims 32-40 in improper Markush format. See Ex parte Markush, 1925 C.D. 126 and In re Weber, 198 USPQ 334. The method claims are improperly joined as the claimed methods require the detection of distinct target molecules (i.e. IL-1 nucleic acids and IL-1 proteins). A reference against one target molecule would not be a reference against the other target molecule . Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims do not recite proper species. **Upon election, Applicants are required to amend the claims to set forth only the elected inventive groups.**

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-7 and 77-79, drawn to methods to detect a predisposition to developing restenosis, classified in Class 435, subclass 6.

II. Claims 8-15, drawn to kits comprising primers, classified in Class 536, subclass 24.33.

III. Claims 16-32, 43-59, 77 and 78, drawn to methods of treating restenosis and methods for selecting a therapeutic regimen , classified in Class 514, subclasses 1 and 44.

IV. Claims 33-42, drawn to method for determining the effectiveness of treatment by measuring IL-1 protein levels, classified in Class 435, subclass 7.1.

1. ***RESTRICTION***

Prior to setting forth the restriction requirement, it is pointed out that Applicants have presented the methods of claims 32-40 in improper Markush format. See Ex parte Markush, 1925 C.D. 126 and In re Weber, 198 USPQ 334. The method claims are improperly joined as the claimed methods require the detection of distinct target molecules (i.e. IL-1 nucleic acids and IL-1 proteins). A reference against one target molecule would not be a reference against the other target molecule . Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims do not recite proper species. **Upon election, Applicants are required to amend the claims to set forth only the elected inventive groups.**

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III. Claims 16-32, 43-59 and 77, drawn to methods of treating restenosis and methods for selecting a therapeutic regimen , classified in Class 514, subclasses 1 and 44.

IV. Claims 33-42, drawn to method for determining the effectiveness of treatment by measuring IL-1 protein levels, classified in Class 435, subclass 7.1.

V. Claims 33-42, drawn to method for determining the effectiveness of treatment by measuring IL-1 nucleic acid levels, classified in Class 435, subclass 6.

VI. Claims 33-42, drawn to method for determining the effectiveness of treatment by measuring IL-1 protein activity, classified in Class 435, subclass 4.

VII. Claims 60-66, drawn to a method for detecting a compound that effects the interaction of IL-1 and an IL-1 binding partner, classified in Class 435, subclass 7.1.

VIII. Claims 67-76, drawn to methods for identifying compounds that decrease IL-1 activity, classified in Class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the kits of claim II can be used in a materially different process such as for methods which analyze the sequence of the IL-1 gene and methods which diagnose other types of diseases, such as asthma .

Inventions I and III-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to patentably distinct methods which require different reagents,

and/or have different objectives. Invention I is drawn to methods for diagnosing a vascular disorder and requires detecting an ILb, IL-1RN (VNTR) or Il-RN (2018) allele. Invention III is drawn to a method for selecting an appropriate therapeutic for an individual that has a vascular disorder by selecting a therapeutic that compensates for a causative functional mutation that is in linkage disequilibrium with the vascular disorder associated allele and thereby invention III requires identifying a causative functional mutation and selecting a therapeutic that compensates for said mutation. Inventions IV-VI are drawn to methods for determining the effectiveness of treating an individual for a vascular disease and requires administering a drug to a subject and detecting IL-1 protein levels (invention IV), IL-1 nucleic acid levels (invention V) or IL-1 activity (invention VI). Drugs which alter IL-1 protein levels, IL-1 nucleic acid levels and IL-1 activity have different mechanisms of action and are patentably distinct from one another, and methods for detecting protein levels, nucleic acid levels and IL-1 activity involve different reagents and require performing different method steps. Invention VII is drawn to a method for screening for a therapeutic for treating or preventing a vascular disorder and requires the use of IL-1 protein, an IL-1 binding partner and a test compound and requires determining whether a test compound prevents or allows for the formation of a complex between IL-1 and an IL-1 binding partner. Invention VIII is drawn to a method for identifying a therapeutic for treating or preventing a vascular disorder and requires the use of a cell or cell extract which expresses IL-1 and the use of a test compound and involves determining whether the test compound decreases agonist or antagonist bioactivity.

Inventions II and III, II and IV, II and V, II and VI, II and VII and II and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together because the kits of invention II are not required to practice the methods of inventions III-VIII and the kits of invention II can be used in materially different processes such as in general methods for determining the sequence of the IL-1 gene and in methods for diagnosing other types of diseases such as asthma.

Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-VIII require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

A telephone call was made to Beth Arnold on April 23, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

July 2, 2001

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER